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Long-Term Follow-Up of Anatomic Graduated Component Total Knee Arthroplasty

A 15- to 20-Year Survival Analysis

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Abstract: The aims of this study were to determine survival rate, the clinical performance, and radiologic results of an Anatomic Graduated Component (AGC) total knee arthroplasty (TKA). Survival analysis was assessed by analyzing all hospital records of 211 AGC TKAs in 177 patients after 15 to 20 years. The survival rate was 87%, with *failure* defined as revision for any reason including infection. The main reasons for failure were infection and failure of the metal-backed patellar component. Clinical evaluation of 30 patients (33 TKAs) and questionnaires of 20 patients (23 TKAs) were taken, showing moderate to good results (mean Knee Society Score, 51; mean Western Ontario and McMaster Universities Osteoarthritis index, 82; mean University of California Los Angeles score, 4). Radiologic evaluation of 13 TKAs in 12 patients showed that none was suspect for loosening. Three knees showed significant medial wear but no clinical complaints. In conclusion, this is one of the first studies showing that AGC total knee prosthesis has good results 15 to 20 years after surgery. **Keywords:** AGC, survival, revision, knee, arthroplasty.
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Total knee arthroplasty (TKA) is a highly effective procedure that provides reliable relief from pain, improved physical function, and a high level of patient satisfaction in patients with advanced knee osteoarthritis [1]. Long-term follow-up studies are scarce, especially of young patients. Anatomic Graduated Component (AGC; Biomet, Inc, Warsaw, Ind) TKA is a commonly used implant in the treatment of advanced osteoarthritis and rheumatoid arthritis. Research on this prosthesis and its survival and functional outcome in studies with up to 15 years of follow-up has been conducted [2-8]. The aims of this study were to determine survival rate, clinical performance, and radiologic results 15 to 20 years after an AGC TKA.

Materials and Methods

This is a retrospective cohort study. All patients who received a TKA between 1987 and 1992 at Martini Hospital in Groningen, the Netherlands, were included. The implant used was the AGC TKA (Biomet). This is a cemented posterior-cruciate ligament-retaining prosthesis with a monoblock tibial component and fixed polyethylene bearing. The concept was introduced in 1983, and from 1986 onward, the design has essentially remained unchanged [8]. A metal-backed patella was used until 1990; since then, a polyethylene-pegged patellar button has been used because of a high incidence of aseptic loosening of the metal-backed patellar button observed in the study by Ritter et al [9].

Outcomes

The primary outcome measure was survival of the TKA. *Failure* was defined as having had revision surgery. *Revision* was defined as removal or exchange of a prosthetic component for any reason including infection. Reasons for revision were assessed. Secondary outcome measures included the functional scores of the Knee Society Score (KSS) [10] as a physician-based outcome measure, the Western Ontario and McMaster Universities Osteoarthritis index (WOMAC) [11,12] as a disease-specific patient-reported outcome measure, and

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the Short-Form 36 score [13] to determine generic health-related quality of life. All scores range from 0 to 100, with 100 representing the best result. The University of California Los Angeles (UCLA) score was added to determine physical activity status on a scale ranging from 0 (wholly inactive) to 10 (regularly participates in impact sports) [14].

Radiologic Investigation

X-rays were taken in a standing position in both directions. The Roentgenographic Evaluation System was used to quantify the number of radiolucent lines representing loosening of the interface between component with cement and bone [15]. The interface of each component is divided into a number of zones. The scoring system for each of the components is determined by measuring the width of the radiolucent lines for each zone in millimeters. Four or less millimeters of radiolucent lines is not significant, 5 to 9 mm should be followed closely for progression, and 10 mm or more signifies possible or impending failure of the component.

Study Procedure

Hospital records were reviewed, and demographic data such as age at surgery, sex, indication for surgery, treated side, complications, and whether or not revision surgery had taken place were noted in a database. Of the patients who had died at the time the study was conducted, date of death was noted as well as the other demographic data. If no problems with the TKA were described at the last visit, we presumed that there were none at the time of death because the arthroplasty had not been revised.

All living patients were invited to participate in the study. Those who wanted to participate visited the outpatient clinic. Whenever it was not possible to come to the outpatient clinic (mainly because of transportation problems), these patients were visited by the examiner at their homes. Whenever patients did not want to come to the clinic or be visited at their homes, they were interviewed by telephone. Those patients who visited the outpatient clinic underwent a physical examination, and the KSS was completed. During this visit, the WOMAC, Short-form 36, and UCLA questionnaires were filled out by the patients and their families, and a standing anteroposterior and lateral x-ray was taken. Patients visited at home were administered the 4 questionnaires and given a physical examination but had no x-rays taken. For patients who were interviewed by telephone, the KSS telephone score was completed. This telephone interview simulates the KSS [8].

The study was approved by the local medical ethical committee, and all participating patients filled out an informed consent form.

Statistical Analysis

Survival data were determined for implant survival [16]. A life table was constructed for survival analysis of the implant using the technique described by Murray et al [17]. To construct this life table, the number of TKAs being followed and the number of failures were determined for each year. The first year starts with the total number in the study; in subsequent years, this number fall away gradually to zero as a result of death or revision surgery (failure). For each successive year, the failure rate was calculated from the number of failures and the "number at risk." *Failure* was defined as revision of the prosthesis for any cause. The life table method is advantageous because the failure rate is determined for each successive year, and details for each year about the number of TKAs followed, the number of failures, and the number of deceased are provided. By contrast, the product-limit method (Kaplan and Meier) recalculates the survival rate each time a failure occurs and does not provide details for each successive year.

The influence of sex, indication being primary osteoarthritis or other, age at the time of operation, type of patellar button (metal-backed or polyethylene), and bilaterality were evaluated in a multivariate logistic regression analysis. Means and standard deviations were calculated for the total scores of the WOMAC, SF-36, UCLA, and KSS questionnaires.

Results

The cohort (Fig. 1, flowchart) consists of 227 TKAs in 192 patients who underwent a primary AGC TKA

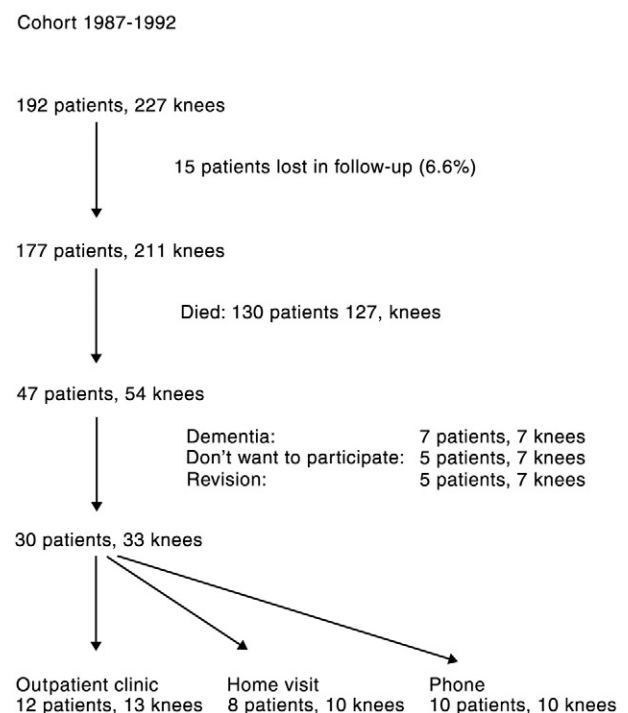


Fig. 1. Patient flowchart.

between 1987 and 1992. Hospital records of 15 patients (16 TKAs) who had died were lost, and these patients were excluded (6.6%). The study population, therefore, consisted of 211 knee arthroplasties in 177 patients.

There were 34 patients with bilateral TKA. The average (SD) age of the patients was 72.6 (8.9) years, with a range of 21 to 91 years at the time of surgery. Twenty-four knee arthroplasties were done in male patients (11%) and 187 in female patients (89%). Most indications were primary osteoarthritis (81.5%) and rheumatoid arthritis (14.2%); other indications were posttraumatic arthritis (1.9%), secondary osteoarthritis after tuberculous arthritis (1.0%), rachitis (0.5%) or septic arthritis (0.5%), and avascular necrosis (0.5%). All 3 components were cemented, and in all but 3 (after prior patellectomy), the patella was resurfaced. Most of the patellae (148; 71%) were resurfaced with a polyethylene dome patella; 60 (29%) were resurfaced with a metal-backed patella.

At the time this study was conducted, 130 patients (74%) with 157 TKAs had died, leaving 47 patients with 54 knee arthroplasties available for clinical analysis.

Primary Outcome

Survival analysis in this series showed a survival rate of 87% at 20 years (Fig. 2; Table 1). Of the 211 knee arthroplasties, 17 were revised (8.1%) for the following reasons: 5 TKAs were revised because of infection; in 8 TKAs, the patella was removed because of aseptic loosening; in 1 knee, the patella was removed after a patellar fracture caused by loosening of the patellar component; 2 TKAs were revised because of aseptic loosening of the tibial plateau; and 1 knee was revised because of aseptic loosening of the tibial plateau as

Table 1. Life Table AGC Survival

Interval Start Time	Statistics				Cumulative Survival Rate
	No. at Start	Deceased	No. at Risk	Revisions	
0-1	211	0	211	0	1.00
1-2	211	4	209	1	1.00
2-3	206	6	203	3	0.98
3-4	197	7	193.5	3	0.97
4-5	187	7	183.5	0	0.97
5-6	180	7	176.5	2	0.95
6-7	171	13	164.5	0	0.95
7-8	158	16	150	0	0.95
8-9	142	9	137.5	1	0.95
9-10	132	8	128	0	0.95
10-11	124	12	118	0	0.95
11-12	112	12	106	3	0.92
12-13	97	9	92.5	1	0.91
13-14	87	10	82	1	0.90
14-15	76	10	71	1	0.89
15-16	65	18	56	1	0.87
16-17	46	17	37.5	0	0.87
17-18	29	11	23.5	0	0.87
18-19	18	8	14	0	0.87
19-20	10	5	7.5	0	0.87
20-21	5	4	3	0	0.87
21-22	1	1	0.5	0	0.87

well as the patella. In 7 of the 8 knees that were reoperated because of aseptic loosening of the patella, this involved a metal-backed patella, which failed at an average of 6.1 years. No revisions had taken place because of aseptic loosening of the femoral component. Overall, revision surgery took place at an average of 7.5 years (range, 1-15 years) after a primary operation. No revision was done because of extensive wear of the polyethylene.

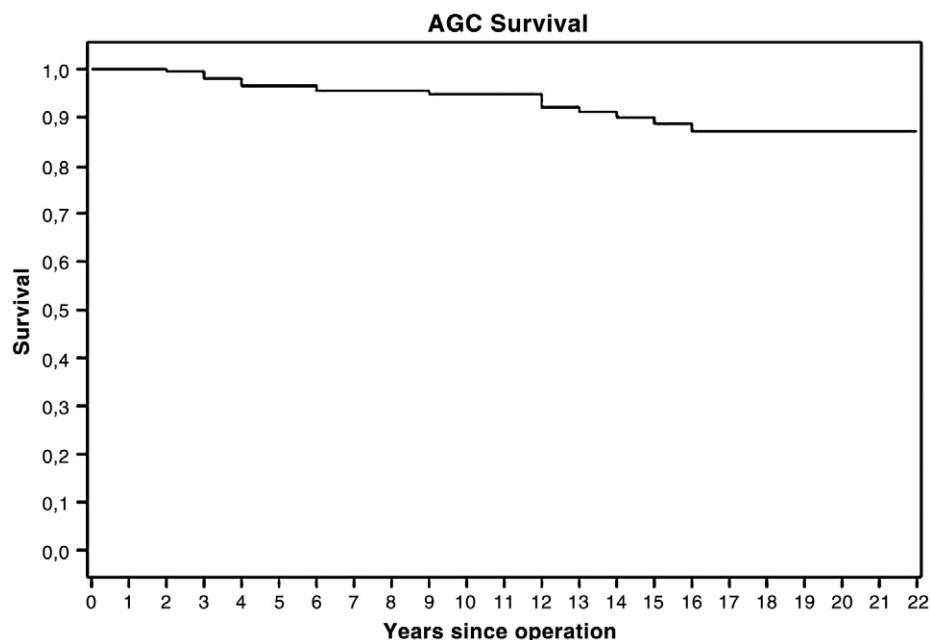


Fig. 2. Survival analysis curve of the AGC TKA.

The multivariate logistic regression analysis showed that indication (primary or secondary osteoarthritis), sex, age at operation, type of patellar component (metal-backed or polyethylene), and bilaterality were not significant risk factors for failure; all 95% confidence intervals of the odds ratios included 1 risk factor (Table 2).

Secondary Outcomes

At the time of the investigation, 47 patients (54 TKAs) were still alive (Fig. 1). Seven patients with 7 TKAs had dementia and were, therefore, excluded. Five patients with 7 TKAs did not want to participate. Seven TKAs in 5 patients had been revised. This leaves 30 patients with 33 TKAs for analysis. Twelve patients (13 TKAs) visited the outpatient clinic, 8 patients (10 TKAs) were visited at home by the examiner, and 10 patients (10 TKAs) were interviewed by telephone.

The KSS was scored in 30 patients (33 TKAs). The mean (SD) KSS was 51 (20) points. Of the 20 patients (23 TKAs) who visited the outpatient clinic or were visited at home, the mean (SD) function score was 25.9 (31.5), the mean (SD) knee score (physical examination) was 77.3 (16.4), and the mean (SD) flexion of the knees was 102° (13.4 °). The WOMAC, UCLA, and SF-36 were scored in 20 patients (23 TKAs). The mean (SD) WOMAC score was 82 (16) (pain, 86.6; stiffness, 91.5; function, 64.4). The mean (SD) UCLA score was 3.9 (1.9), representing doing mild activities regularly. The mean (SD) SF-36 score on physical health was 60 (21) of 100.

Radiographs of the 12 patients (13 TKAs) who visited the outpatient clinic were taken. In all but 2 knee prostheses, radiolucent lines were observed at the prosthetic interface. No prostheses had clinical symptoms; therefore, none of the components were suspected to be loose at radiologic evaluation. Three tibial components had significant polywear (>4 mm) at the medial side.

Table 2. Multivariate Logistic Regression Analysis of Risk Factors for Revision

	Odds Ratio	95% Confidence Interval	
		Lower	Upper
Being male*	0.93	0.19	4.55
Age at operation (y)	0.97	0.92	1.02
Indication not being primary osteoarthritis [†]	1.31	0.36	4.79
Metal-backed patella [‡]	2.30	0.78	6.72
Bilaterality [§]	1.04	0.33	3.25

* Female as reference.

[†] Primary osteoarthritis as reference.

[‡] Polyethylene patella as reference.

[§] Unilaterality as reference.

Discussion

The AGC prosthesis that we used between 1987 and 1992 is a posterior-cruciate ligament-retaining total condylar TKA. The design of this prosthesis has essentially remained an unchanged design since 1986. We found an 87% survival after 15 to 20 years.

Failure was defined as removal or exchange of any prosthetic component for any cause including infection. This definition is simple, reproducible, and objective and is also used in other studies [3,7,8,18-20]. Not all survival studies include infection in the definition of failure, though [2,6,21,22], which may explain different outcomes on survival in multiple studies.

Main reasons for failure in this series were infection and aseptic loosening of the metal-backed patellar component; therefore, its use was suspended in 1991. Emerson et al [2] also found a higher number of revisions in the metal-backed patellar group at an average of 6.7 years after surgery. Stulberg et al [23] analyzed revisions that appeared at an average of 14 months. In our study, the metal-backed patella failed at an average of 6.1 years, which is in line with other studies. Furthermore, in our study, there were 2 revisions because of failure of the tibial component, 1 because of failure of the tibial and patellar components, and no revisions because of failure of the femoral component; no patients needed revision surgery because of extensive wear of the polyethylene (no instability and no loosening). Other studies have also found that the AGC prosthesis has proved to show no clinical symptoms of significant wear [2,24]. The Swedish Knee Arthroplasty Register shows the AGC to be one of the least revised TKA [25].

In comparison with prior studies on the ACG TKA, our study, together with Ritter [26], is unique because of its long-term follow-up. Ritter describes a survival rate of 97.8% after 20 years and attributes the success of the AGC implant to its relatively unconstrained articular geometry and the durability of a nonmodular metal-backed tibial component with compression-molded polyethylene. Ritter's higher survival rate may be attributed to his correction for preoperative valgus deformity, which seemed to have a significant influence on survival. Because these preoperative data were not available to us, we could not correct for this to see if this indeed explains the difference in survival between the 2 studies.

There are several other survival studies of the AGC TKA with shorter follow-up. Worland et al [8] report 96.9% survival at 14 years in a study group of 562 TKAs with revision for any reason as the end point. Emerson et al [2] report survival of 95% at 11.4 years in 62 TKAs with revision for any reason except sepsis. They only included the living patients. Ritter et al [22] report 98% survival at 10 years with revision for any reason except sepsis. In a different study, Ritter et al [6] report survival of 98% at 15 years in 4583 TKAs with revision for any

reason except sepsis. Himanen et al [3] report 95% survival at 10 years (mean follow-up, <5 years) in a Finnish population of 8467 TKAs. Schröder et al [7] report 97% survival at 10 years in 114 TKAs with revision for any reason as the end point. Compared with these studies, our results of survival are a little lower after longer follow-up but comparable after a likewise follow-up period; just like Emerson et al [2], we also report survival of 95% after 11 years.

In a Norwegian follow-up study of TKAs, the AGC had a survival rate of 97% at 5-year follow-up, comparable with 5 other cemented tricompartment total knee prostheses [5]. This is the same as in our study: at 5 years, we also have a survival rate of 97%.

There are few studies of other designs of total knee prostheses with a follow-up of more than 15 years. Rodricks et al [19] report 91.5% survival of 63 press-fit condylar total knee arthroplasties at 14 to 17 years (average, 15.8 years). Goldberg and Kraay [18] report 87% survival of 124 Miller Galante I (Zimmer, Warsaw, Ind) total knee arthroplasties at 14 to 17 years. Ma et al [21] report 91.9% survival of 64 total condylar knee arthroplasties at 20 years. Van Loon et al [20] report 87% survival of 77 GSB-II (Sulzer Medica, Winterthur, Switzerland) total knee arthroplasties at 15 years. Overall, these data seem comparable with our results, yet comparison is difficult because of different definitions of failure. Some studies include infections as failures, and others exclude infections because they only want to assess the mechanical aspects of the prosthesis.

We determined pain and functional scores as a way to investigate whether the prosthesis not only survived but is also performing well. The results show that patients have little pain (WOMAC pain score, 86.6). Physical examination scores are also high (knee score KSS, 77.3; mean flexion, 102°). Functional scores (WOMAC function score, 64.4; UCLA, 3.9) show that patients have some limitations during activities of daily living and are mildly active regularly. This leads to the conclusion that the prosthesis performs generally well, but patients are only mildly active, which can be due to other factors unrelated to their prosthesis.

This is a 15- to 20-year survival study in a group of patients whose average (SD) age at the time of surgery was 72.6 (8.9) years. Many patients (74%) died before this study was conducted. If the last visit to our clinic was uncomplicated, we assumed that there were no problems with the prosthesis until the patient died. This is a limitation of our study and may have led to an overestimation of the survival. We had a low rate of lost to follow-up; in this study, we could not find any information beyond 2 months after surgery and, for 6.6% of the patients, the fact that the patient had died. These patients were excluded from our study.

In conclusion, the current study reveals that the AGC posterior-cruciate ligament-retaining TKA has longevity

with a survivorship of 87% at 20 years, with failure defined as revision for any reason including sepsis. This implant system has remained essentially unchanged since 1986. Main reasons for failure were infection and failure of the metal-backed patellar component. This component is no longer used. Polyethylene wear seems not to play a significant role in failure, in contrast with total hip arthroplasty, and no femoral components were revised for aseptic loosening. Long-term follow-up studies of the modern-type implants have to show survival rates after a follow-up period of at least 10 years and must be compared with the older-type TKAs, preferably in randomized trials.

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